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Dated: August 18, 2004

Signature: Shawn P. Foley  
(Shawn P. Foley)

Docket No.:  
CELLTH 3.0-003 CONT CONT XIII  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Warrell et al.

Application No.: 10/758,993

Group Art Unit: 1616

Filed: January 16, 2004

Examiner: A. N. Pryor

For: PROCESS FOR PRODUCING ARSENIC  
TRIOXIDE FORMULATIONS AND  
METHODS FOR TREATING CANCER USING  
ARSENIC TRIOXIDE OR MELARSOPROL

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

### **REQUEST FOR CONSIDERATION OF INFORMATION UNDER 37 CFR § 1.97 (C)**

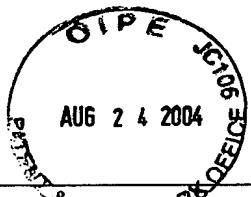
Dear Sir:

It is respectfully requested that the references cited in the enclosed form be considered pursuant to 37 C.F.R. § 1.97(c). Please charge Deposit Account No. 12-1095 in the amount of \$180.00 pursuant to 37 C.F.R. § 1.17(p). In the event that any additional fee is due in connection with the present request, the same should be charged to our Deposit Account No. 12-1095.

Dated: August 18, 2004

Respectfully submitted,

By Shawn P. Foley  
Shawn P. Foley  
Registration No.: 33,071  
LERNER, DAVID, LITTMERBERG,  
KRUMHOLZ & MENTLIK, LLP  
600 South Avenue West  
Westfield, New Jersey 07090  
(908) 654-5000  
Attorney for Applicant



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### INFORMATION DISCLOSURE STATEMENT

Dear Sir:

It is respectfully requested that the references listed on the enclosed form be made of record and considered with respect to the above-referenced U.S. patent application. A copy of each reference was of record in United States Patent 6,723,351, the benefit of which is claimed under §120. Submission of the present Information Disclosure Statement should not be taken as an admission that the cited references are legally available prior art or that the same are pertinent or material.

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No. 12-1095.

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LERNER, DAVID, LITTBENBERG,  
KRUMHOLZ & MENTLIK, LLP

600 South Avenue West  
Westfield, New Jersey 07090  
(908) 654-5000

Attorney for Applicant

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<b>TRADEMARK OFFICE</b> Substitute for form 1449A/B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
Sheet	1	of	5	Application Number	10/758,993
				Filing Date	January 16, 2004
				First Named Inventor	Raymond P. Warrell, Jr.
				Art Unit	1616
				Examiner Name	A. N. Pryor
				Attorney Docket Number	CELLTH 3.0-003 CONT CONT XIII

<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
AA**	US-132,275-B1	10-15-1872	Gettings		
AB**	US-232,807	10-05-1886	Dennett		
AC**	US-3,700,498	10-24-1972	Kanazawa et al.		
AD**	US-4,497,780	02-05-1985	Barin et al.		
AE**	US-5,759,837	06-02-1998	Kuhajda et al.		
AF**	US-2002/0183385	12-05-2002	Ellison et al.		
AG**	US-6,720,011	04-13-2004	Zhang, Ting-Dong		
AH**	US-6,770,304	08-03-2004	Warrell et al.		
AI**	US-2003/0099719	05/2003	Warrell et al.		
AJ**	US-6,723,351	04-20-2004	Warrell et al.		
AK**	US-6,773,792	05-11-2004	Lu		

<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
BA	JP-51-88620		03-08-1976		
BB	WO-95/01789		01-19-1995		
BC	CN-1133725		10-23-1996		
BD	CN-1131037		09-18-1996		
BE	CN-1122700		05-22-1996		
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BG	CN-1119113		03-27-1996		
BH	CN-1061908		06-17-1992		
BI	CN-1121807		05-08-1996		
BJ	CN-1079391		12-15-1993		
BK	WO-94/02103		02-03-1994		
BL	FR-2 539 993		03-31-1994		
BM	DE-43 17 331		12-01-1994		
BN	WO-95/22336		08-24-1995		
BO	LV-11667		06-20-1997		
BP	WO-94/02108		02-03-1994		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	CA	CUTLER et al., Article IV, American Journal of the Medical Sciences, pp. 74-84, January 1878			
	CB	FORKNER et al., "Arsenic as a therapeutic agent in chronic myelogenous leukemia", Jour.			

Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO				<b>Complete if Known</b>	
				Application Number	10/758,993
				Filing Date	January 16, 2004
				First Named Inventor	Raymond P. Warrell, Jr.
				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	2	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XIII

		A.M.A. 97(1):3-5, 1931	
	CC	STEPHENS, et al., "The therapeutic effect of solution of potassium arsenite in chronic myelogenous leukemia", University of Rochester, pp. 1488-1502, 1936	
	CD	NEUBAUER, "Arsenical cancer: a review", Arsenic Committee of the Medical Research Council, pp. 192-251, 1947	
	CE	SHIBUYA, "Studies on experimental arsenious acid poisoning", Tokyo Jikeikai Ika Daigaku Zasshi, 86(4):653-675, 1971	
	CF	PORIES et al., "Trace elements that act to inhibit neoplastic growth", Annals of New York Academy of Sciences, 199:265-273, June 25, 1972	
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	CJ	Arsenic, Environmental Health Criteria, 18, Geneva: WHO, 1981	
	CK	CUZICK et al., "Medicinal Arsenic and Internal Malignancies", Br. J. Cancer, 45:904-911, 1982	
	CL	QI and BI, "Method for Removing As <sub>2</sub> O <sub>3</sub> from Realgar, Chung Yao Tung Pao, 8(5):21-22, 1983	
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	CP	SHIMOTSUURA et al., "Studies on the Antineoplastic Actions of As <sub>2</sub> O <sub>3</sub> ", Shikwa Gakuho, 86:1237-1253, 1986	
	CQ	YAMAMOTO et al., "Tumorigenicity of Inorganic Arsenic Compounds Following Intratracheal Instillations to the Lungs of Hamsters", Int. J. Cancer 40:220-223, 1987	
	CR	LEE et al., "Induction of Gene Amplification by Arsenic", Science, 241: 79-81, 1988	
	CS	LI et al., "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma", Chinese J. Oncology, 10:61-62, 1988	
	CT	SUN, HONGDE et al., "32 Cases of Acute Early Granulocytic Leukemia Treated with Ai-Ling No. 1 in Combination with Chinese Medical Practice of Pattern Identification", Zhongguo Zhongxiyi Jiehe Zazhi, Vol. 12(3), 170-171, 1992	
	CU	PENG, ZHANG et al., "Treatment of Acute Promyelocyte Leukemia with Intravenous Arsenic Trioxide", Chinese Journal of Hematology, Vol. 17, Translation, February 1996	
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	CX	Goodman & Gilman's "The Pharmacological Basis of Therapeutics", Ninth Edition, McGraw-Hill, Health Professions Division, pp. 1659-1662	
	CY	"Inorganic Arsenic Compounds Other Than Arsine Health and Safety Guide", Health and Safety Guide No. 70, WHO, Geneva 1992	
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	CA1	AKAO et al., "Arsenic Induces Apoptosis in B-cell Leukemic Cell Lines in Vitro: Activation of Caspases and Down-regulation of Bcl-2 Protein", British J of Hematology, 102, 1055-1060, 1998 ©Blackwell Science Ltd.	
	CB1	ANDRE et al., "The PML and PML/RAR $\alpha$ . Domains: From Autoimmunity to Molecular Oncology and From Retinoic Acid to Arsenic", Experimental Cell Research, 229:253-260, 1996 ©Academic Press, Inc. 1996	
	CC1	Chemical Abstract, 63-Pharmaceuticals 11:317, 111:219272j and 111:219276p, 1987-1991	

Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO				<b>Complete if Known</b>	
				Application Number	10/758,993
				Filing Date	January 16, 2004
				First Named Inventor	Raymond P. Warrell, Jr.
				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	3	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XIII

	CD1	CHEN et al., "In Vitro Studies on Cellular and Molecular Mechanisms of Arsenic Trioxide (As <sub>2</sub> O <sub>3</sub> ) in the Treatment of Acute Promyelocytic Leukemia: As <sub>2</sub> O <sub>3</sub> induces NB <sub>4</sub> Cell Apoptosis with Down Regulation of Bcl-2 Expression and Modulation of PML-RAR $\alpha$ /PML proteins", Blood 88(3): 1052-1061, Aug. 1996. ©American Society of Hematology 1996	
	CE1	CHEN et al., "Use of Arsenic Trioxide (As <sub>2</sub> O <sub>3</sub> ) in the Treatment of Acute Promyelocytic Leukemia (APL):I. As <sub>2</sub> O <sub>3</sub> Exerts Dose-Dependent Dual Effects on APL Cells", Blood 89(9):3345-3353, 1997 ©The American Society of Hematology 1997	
	CF1	CHUNG et al., "Influence for Carcinoma Cell and Lymphatic Cell of Acetyl Arsonate", Yakhak Hoeji 40(5):599-607, 1996 (Abstract Only)	
	CG1	DE THE "L'oxyde d'arsenic: apres l'acide retinoique, un nouveau traitement cible dela leucemie aigue promyelocytaire" Medecine/Sciences, 13:867-71, 1997	
	CH1	Dictionary of Inorganic Compounds, vol. 1, Ac-C <sub>10</sub> , IC-0006667-IC-000671 (1992)	
	CI1	FLAMIGNI et al., "Effect of Sodium Arsenite on the Induction and Turnover of Ornithine Decarboxylase Activity in Erythroleukemia Cells", Cell Biochemistry and Function 7:213-217, 1989	
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	CK1	GERMOLEC et al., "Arsenic Induces Overexpression of Growth Factors in Human Keratinocytes", Toxicology and Applied Pharmacology, 141:301-318, 1996 ©Academic Press, Inc., 1996	
	CL1	HUANG et al., 1995, "The Clinical Study of QINGDAI Tablet for Treating Acute Promyelocytic Leukemia", China Magazine of Hematology, 16(1):26	
	CM1	KONIG et al., "Comparative Activity of Melarsoprol and Arsenic Trioxide in Chronic B-Cell Leukemia Lines", Blood 90(2):562-570, 1997. ©The American Society of Hematology 1997	
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	CO1	LU et al., "Effective treatment of AML-M3 (APL) and Their Remission Maintenance with Realgar: A Pilot Clinical and Laboratory Study on 38 Patients", Blood, 90 (10 Suppl. 1, part 1):416A, #1849, 1997	
	CP1	LU et al., "Study of Reaglar in the Treatment of Acute Promyelocytic Leukemia (APL)-a pilot clinical and laboratory study on 32 Patients", China-Korea Medical Conference '97, 1997	
	CQ1	MERVIS, "Ancient Remedy Performs New Tricks", Science 273:578, 1996	
	CR1	NEUBAUER, "Arsenic Cancer: A Review", Arsenical Cancer, Arsenic Committee of the Medical Research Council, pp. 192-251, 1947	
	CS1	REICHL et al., "Effect of Arsenic on Cellular Metabolism after Single or Repeated Injection in Guinea Pigs", Arch. Toxicol., Suppl. 13, p. 363-65, 1989	
	CT1	Remington's Pharmaceutical Sciences, Mack Publishing Co., Easton, PA, pp. 1570-1580, 1990	
	CU1	SCHENK, Handbook of Preparative Inorganic Chemistry, 1:603, G. Brauer, Ed., Academic Press, New York, 2.sup.nd Edition, 1963	
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	CW1	SOIGNET et al., "Complete Remission after Treatment of Acute Promyelocytic Leukemia with Arsenic Trioxide", J of Medicine 339:19, 1998 . ©Massachusetts Medical Society 1998	
	CX1	TRELEAVEN et al., "Arsenic and Ayurveda", Leukemia and Lymphoma, 10:343-345, 1993	
	CY1	USP Dictionary of USAN and International Drug Names, United States Pharmacopeial Conventions, Inc., Rockville, MD p. 59, Nov. 1994.	
	CZ1	WANG et al., "Studies on Chemically Preventing Leukemia", Ghung Hua Chung Liu Tsa Chih, 11(3):207-210, 1989	
	CA2	XIANG et al., "60 Cases of Treating Acute Promyelocytic Leukemia by QINGDAI Tablet", Med. J. Chin. PLA 20(3):227-229, 1995	

Examiner Signature		Date Considered	
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Substitute for form 1449A/B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	4	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XIII
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	CB2	YUAN et al., "Research on Traditional Methods for Purifying Realgar", Chung Yao Tung Pao, 13(8):23-26, 1988	
	CC2	YUAN et al., "Exploring Methods for Purifying Realgar", Chung Yao Tung Pao, 13(8):17-21, 1988	
	CD2	ZHANG et al., "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma," Chinese J. Oncology, 10:61-62, 1988	
	CE2	ZHANG et al., "Treatment of Acute Promyelocytic Leukemia with "713": Clinical Observations and Study of Action Mode on 117 patients", J. Harbin Medical Univ. 29(3):243, 1995	
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	CG2	ZHU et al., "Arsenic-induced PML Targeting Onto Nuclear Bodies: implications for the treatment of acute promyelocytic leukemia", Proc. Natl. Acad. Sci. 94:3978-3983, 1997, ©The National Academy of Sciences of the USA 1997	
	CH2	"Letter on Historical Facts Regarding the Development of Ai Ling No. 1 and the Clinical Use of Arsenic Trioxide in the Treatment of Acute Promyelocytic Leukemia and a Study of Its Mechanism", Heilongjiang Branch of the Chinese Medical Association, Mar. 27, 1998.	
	CI2	WANG et al., "Arsenic Trioxide and Melarsoprol Induced Programmed Cell Death in Myeloid Leukemia Cell Lines and Function in PML and PNL-RAR $\alpha$ Independent Manner", Blood, 92(5):1497-1504, 1998	
	CJ2	USP Dictionary of USAN and International Drug Names, United States Pharmacopeial Conventions, Inc., Rockville, MD, p. 59, Nov. 1995.	
	CK2	WANG et al., "Arsenic and the Treatment of Leukemia", J Harbin Medical Univ., vol. 31, No. 5, Oct. 1997	
	CL2	SMORENBURG et al., "Randomized Cross-Over Evaluation of Body-Surface Area-Based Dosing Versus Flat-Fixed Dosing of Paclitaxel", J. Clin. Oncology, 21:197-202 (2003)	
	CM2	VOISEN et al., "Extrapolation of Animal Toxicity to Humans: Interspecies Comparisons in Drug Development", Regulatory Toxicology and Pharmacology, 12:107-116 (1990)	
	CN2	FREIRICH et al., "Quantitative Comparison of Toxicity of Anticancer Agents in Mouse, Rat, Hamster, Dog, Monkey and Man", Cancer Chemotherapy Reports, 50:219-244 (1966)	
	CO2	GURNEY, "How to Calculate the Dose of Chemotherapy", Brit. J. Cancer, 86:1297-1302 (2001)	
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	CQ2	AU et al., "Arsenic Trioxide in Comparison with Chemotherapy and Bone Marrow Transplantation for the Treatment of Relapsed Acute Promyelocytic Leukaemia", Annals of Oncology, 14:752-757 (2003)	
	CR2	ZHANG et al., "Pathologic, Cytogenetic and Molecular Assessment of Acute Promyelocytic Leukemia Patients Treated with Arsenic Trioxide (As <sub>2</sub> O <sub>3</sub> )", Modern Pathology; (2000); pp. 954-961	
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<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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